

IN THE UNITED STATE DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

DR. PATTY YOUNG, M.D.,
Dba PREMIER PLASTIC
SURGERY OF TEXAS,

Plaintiff,

v.

CUTERA, INC.,

Defendant.

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Civil Action No. 4:19-cv-00388

**DEFENDANT CUTERA, INC.'S PRE-TRIAL PROPOSED
FINDINGS OF FACT AND CONCLUSIONS OF LAW**

In accordance with the Court's Amended Docket Control Order, Defendant Cutera, Inc. ("Defendant" or "Cutera") submits the following pre-trial proposed Findings of Fact and Conclusions of Law. Defendant reserves the right to revise or amend these proposed Findings of Fact and Conclusions of Law after the close of evidence.

FINDINGS OF FACT

1. Plaintiff Patty K. Young ("Plaintiff") is a physician with a plastic surgery practice in Plano, Collin County, Texas.

2. Defendant Cutera, Inc. ("Cutera") is a Delaware corporation with its principal place of business in California. Defendant Cutera, Inc., designs, manufactures, and sells energy-based aesthetic systems, including the truSculpt® 3D ("truSculpt"), in the United States and abroad.

3. The truSculpt is a non-invasive, monopolar radiofrequency (RF) system that utilizes proprietary software. RF systems, such as the truSculpt, are designed to generate heat

energy targeting adipocytes, which are subcutaneous cells that store fat, while maintaining lower skin surface temperatures.

4. Prior to introducing the truSculpt into the marketplace, Cutera conducted controlled studies related to the efficacy of this device. The studies reflected that all subjects achieved a statistically significant reduction in their submental circumference and thickness after treatments. The studies showed that the truSculpt platform is effective and safe for submental fat reduction.

5. In 2012, the United States Food and Drug Administration (“FDA”) cleared Cutera’s first truSculpt device for marketing and sale in the United States allowing for it to be marketed providing temporary reduction in the appearance of cellulite. In 2017, the FDA also cleared Cutera to market its RF technology as providing a temporary reduction in circumference of the abdomen. In 2018, the FDA further cleared Cutera to market its RF technology as providing non-invasive lipolysis (breakdown of fat).

6. On March 24, 2017, Plaintiff entered into a Purchase Agreement with Cutera for the purchase of a truSculpt. Prior to her purchase, Dr. Young kept abreast of the development of RF technology for non-invasive fat reduction by attending conferences and reading medical journals where this technology was discussed.

7. In the weeks leading up to her purchase of the truSculpt, Plaintiff met with Matt Falkenstein, a representative for Cutera, on two or three occasions. During these meetings, Falkenstein provided Plaintiff with information related to the qualities and characteristics of the truSculpt, its intended use, and studies related to its effectiveness. Falkenstein communicated to Plaintiff, in part, that the studies reflected that patients experienced low pain and, on average, achieved 24% fat reduction in the treated areas, with the maximum effect occurring 12 weeks

after treatment. Falkenstein further communicated potential side effects, including pain, discomfort, redness, erythema, mild burns, swelling, and lumps.

8. Plaintiff also spoke with a physician named Dr. Hughes in Colorado that used the device. Dr. Hughes communicated to Plaintiff that the device was easy to use and was fairly effective at achieving fat reduction. Plaintiff subsequently agreed to purchase the truSculpt.

9. On March 24, 2017, Falkenstein visited Plaintiff's office and presented her with the Purchase Agreement, which was accompanied by Cutera – Terms and Conditions. The terms and conditions disclaimed all warranties, express or implied, other than the explicit warranties contained therein. Plaintiff executed the Purchase Agreement.

10. Cutera delivered the truSculpt to Dr. Young's office on June 13, 2017. Upon delivery, Plaintiff was also provided with an operator manual and treatment guidelines. Therein, Plaintiff was further informed of potential side effects from use of the truSculpt, including blistering, burns, discomfort and pain, lumps, redness (erythema), swelling, and tenderness, and she was instructed to advise patients of these potential side effects. Plaintiff read these materials. She was also provided with access to additional informative materials and videos through the website, www.myCutera.com. Plaintiff did not seek to return the truSculpt upon receipt of these materials.

11. Plaintiff and her staff were trained on the use of the truSculpt in June of 2017. During the training session, Plaintiff's staff took turns treating each other with the truSculpt. While some of Plaintiff's staff reported pain and burning sensations, Plaintiff described the treatment as warm and uncomfortable. She did not report severe pain or burning from the treatment. Plaintiff did not seek to return the truSculpt immediately after this training session.

12. Plaintiff and her staff treated patients with the truSculpt from June of 2017 until July of 2018.

13. Prior to performing truSculpt treatments, Plaintiff advised each patient of the potential side effects and required each patient to sign an informed consent form. The informed consent advised patients of potential adverse experiences or risks, including discomfort, pain, redness, swelling, scarring, skin color changes, numbness, and lumps. The form further advised patients it was possible the result of the treatment would be “minimal or not help at all.”

14. A treatment of one part of the body lasted 15 minutes, and if a patient received treatment to multiple parts of their body, the maximum treatment time would last 1 hour.

15. Cutera promptly repaired Plaintiff’s truSculpt after maintenance issues were reported. When Plaintiff encountered certain performance issues and reported them to Cutera, Cutera responded to each service issue and performed the necessary repairs on the device at no additional cost to Plaintiff. After the repairs were completed, the system was noted to be operating within specifications. The service records also indicate that, in August of 2018, a Cutera maintenance technician performed a courtesy calibration check and again found the system operating to specification. Despite conducting a comprehensive test of the system’s calibration and performance, the technician could not duplicate any of the overheating alleged by Plaintiff.

16. In addition, Cutera sent Vice President of Clinical Affairs, Amogh Kothare, to visit Dr. Young and her staff. During his visit, Mr. Kothare inspected the machine, educated Dr. Young’s staff on the proper use of the machine and provided additional training to ensure that they were using the machine in accordance with the guidelines and operator manual. Cutera never charged Dr. Young for this inspection or additional training session.

CONCLUSIONS OF LAW

17. Diversity of jurisdiction exists, and therefore, the Court has jurisdiction of the parties and subject matter for entry of an Order or Judgment herein. Venue is proper in the United States District Court for the Eastern District of Texas, Sherman Division.

18. Plaintiff received the Cutera – Terms and Conditions with the Purchase Agreement. The Purchase Agreement signed by Plaintiff explicitly incorporates these terms and conditions, and thus, the terms and conditions became a part of the contract between Plaintiff and Cutera.

19. Per the unambiguous terms of this contract, Cutera agreed to deliver to Plaintiff one truSculpt in exchange for \$135,000. For this purchase price, Cutera also agreed to provide training, a one-year warranty, and two handpieces. Cutera explicitly warranted that the product would be free from defects and workmanship, and Cutera's sole obligation under this warranty was to repair or replace any defect that was present when the product was first shipped to the customer. The contract explicitly, conspicuously, and unambiguously disclaimed all other warranties, express or implied, and it specifically identified the implied warranties of merchantability and fitness for particular use as being disclaimed.

20. Cutera delivered the truSculpt and handpieces to Plaintiff, provided training to Plaintiff and her staff, and performed warranty repairs. The truSculpt was in good and working condition after each repair.

21. The evidence at trial established that Cutera did not materially breach any express warranties in the contract. The Court also finds that any express or implied warranties outside of the contract were disclaimed, and any claims arising from an alleged breach of those warranties are barred. Accordingly, Cutera is not liable to Plaintiff under any breach of warranty theory,

express or implied. Cutera is likewise not liable to Plaintiff under the Texas Deceptive Trade Practices – Consumer Protection Act (“DTPA”) for any breach of warranty, express or implied.

22. Plaintiff’s other claims made under the DTPA are barred by the economic loss rule. Plaintiff fails to establish any injury from Cutera’s alleged DTPA violations that were separate and independent from the alleged injury caused by Cutera’s alleged failure to deliver the product promised by the contract. Accordingly, Plaintiff’s claim for DTPA violations are barred.

23. Alternatively, Plaintiff has not presented sufficient evidence of unconscionable action on the part of Cutera or violations of DTPA’s laundry list. “Unconscionable action or course of action” means an act or practice which, to a consumer’s detriment, takes advantage of the lack of knowledge, ability, experience, or capacity of the consumer to a grossly unfair degree. Plaintiff is a board-certified plastic surgeon who has been practicing for nearly 30 years. Plaintiff is familiar with various methods for fat reduction, including non-invasive, RF technology. Before her purchase of the truSculpt, Plaintiff attended conferences and read medical journals where RF technology was discussed. Per her own employees, she had been monitoring the development of this technology. There is no evidence that Cutera took advantage of any lack of knowledge, ability, experience, or capacity of Plaintiff to a grossly unfair degree.

24. Also, there was not legally sufficient evidence establishing that Cutera engaged in any false, misleading, or deceptive acts and practices including: representing (both expressly and by omission) that goods or services have characteristics, uses, or benefits which they do not have; representing that goods or services are of a particular standard, quality, or grade when they were of another; representing that an agreement confers or involves rights, remedies, or obligations which it does not have; representing that goods or services have sponsorship or approval they do not have; representing that a guarantee or warranty confers or involves rights or

remedies which it does not have; attempting to obtain a waiver of legal rights without following the law in regard to such waivers; and failing to disclose information concerning goods or services which was known at the time of the transaction when such failure to disclose was intended to induce Plaintiff into a transaction into which Plaintiff would not have entered had the information been disclosed. Accordingly, Cutera is not liable to Plaintiff under the DTPA.

25. Plaintiff's remaining common law causes of action of fraud, fraud in the inducement, and negligent misrepresentation are also barred by the economic loss rule. Similar to her DTPA claim, Plaintiff fails to present any evidence showing that she suffered an injury as a result of Cutera's alleged misrepresentations that was separate and independent from the alleged injury caused by Cutera's alleged failure to deliver the product promised by the contract. Therefore, Plaintiff cannot recover from Cutera under claims of fraud, fraud in the inducement, and negligent misrepresentation.

26. Alternatively, the Court finds Cutera did not make false statements of fact to Plaintiff, and there is no evidence establishing that Cutera made representations to Plaintiff with actual knowledge that those representations were false at the time they were made or that Cutera made those representations without any knowledge of their truth. The Court further finds Cutera exercised reasonable care in its representations to Plaintiff. Accordingly, Cutera is not liable under theories of fraud, fraud in the inducement, and negligent misrepresentation.

27. Judgment shall be, and is hereby, entered in favor of Cutera, Inc.

28. All claims made by Plaintiff against Cutera, Inc. should be, and hereby are, dismissed with prejudice.

29. Cutera, Inc. shall recover its costs expended herein, in an amount to be determined by the Court.

Respectfully submitted,

**SERPE, JONES, ANDREWS,
CALLENDER & BELL, PLLC**

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**ATTORNEYS FOR DEFENDANT
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CERTIFICATE OF SERVICE

This will certify that, on August 21, 2020, a true and correct copy of the foregoing document was forwarded to the following counsel of record pursuant to the Federal Rules of Civil Procedure:

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